DETAILED ACTION

Claims 1, 5-17, 31-34, 39-42, 61, 80-83 and 86-88 are pending in this application.

Applicants' arguments filed November 25, 2009 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Specification

The amendment filed November 25, 2009 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Opaglos® 6000P in paragraph [0027], lines 3 and 5, paragraph [0049] and paragraph [0051] in lines 3 and 14. Opaglos, previously noted in the specification did not indicate a particular product from the array of Opaglos products. It only disclosed "Opaglos".

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112 (first paragraph)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 31 and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 31 and 32 have been amended to recite Opaglos® 6000 P. The specification contains support for "Opaglos" and does not provide support for the specific Opaglos product, Opaglos® 6000 P. This is a new matter rejection.

Claim Rejections - 35 USC § 112 (second paragraph)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 31 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites that the pharmaceutically acceptable oral formulation is substantially free of degradation products associated with exposure of a 5-HT receptor agonist to "ambient moisture". Since the "**ambient moisture**" is not defined in the specification, the meaning is unclear. Turning to the dictionary, the meaning of "ambient" merely means surrounding a subject. Dependent upon where you live and

under what conditions, ambient moisture can vary greatly. The definition from http://encyclopedia.thefreedictionary.com/Ambient+moisture is: the presence of moisture of the surroundings. "Ambient moisture" is a term that may be applied to the outdoors or to any place. Even once a context has been specified, "ambient moisture" may refer to no particular moisture humidity level. The ambient moisture of a place may vary in time as well as space. The temperature at a certain lattitude and longitude in the Sahara Desert will depend on whether it is night or day, windy or still and the location of the hygrometer. These variations and gradations may affect an experiment that extends over a large space or takes place over a long time. The MPEP, 2111.01 [R-2] states that the words of a claim must be given their "plain meaning" unless they are defined in the specification". During examination, the claims must be interpreted as broadly as their terms reasonably allow. In re American Academy of Science Tech Center, F.3d, 2004 WL 1067528 (Fed. Cir. May 13, 2004)(The USPTO uses a different standard for construing claims than that used by district courts; during examination the USPTO must give claims their broadest reasonable interpretation.). This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989); Chef America, Inc. v. Lamb-Weston, Inc., 358 F.3d 1371, 1372, 69 USPQ2d 1857 (Fed. Cir. 2004) (Ordinary, simple English words whose meaning is clear and unquestionable, absent any indication that their use in a particular context changes their meaning, are construed to mean exactly what they say. Thus, "heating the resulting batter-coated dough to a temperature in the range of about 400° F to 850° F" required

heating the dough, rather than the air inside an oven, to the specified temperature.). It is only when the specification provides definitions for terms appearing in the claims that the specification can be used in interpreting claim language. In re Vogel, 422 F.2d 438, 441, 164 USPQ 619, 622 (CCPA 1970). Therefore, since there is no definition in the instant specification of what is meant by the term "ambient moisture", then the meaning from the dictionary is applied,which is "no particular moisture level".

Claims 31and 32 contain the trademark/trade name Opaglos 6000®. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim **does not comply with the requirements of 35 U.S.C. 112, second paragraph.** See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since **the trademark or trade name cannot be used properly to identify any particular material or product.** A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a proprietary blend of ethanol, shellac, beeswax and yellow carnuba wax, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5-17, 31-34, 39-42, 61, 80-82 and 86-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patel et al. U.S. Patent Application Publication No. 2003/0180352 A1 and Oxford U.S. Patent No. 5,037,845 and in view of Remington's Pharmaceutical Sciences, 1975.

Patel et al. teach a formulation comprising 5-HT receptor agonists such as sumatriptan, eletriptan, frovatriptan, naratriptan, rizatriptan and zolmitriptan (paragraphs

46, 60, 106-107, 447, and 448) for oral use (paragraph 272) comprising a core material (paragraphs 316, 350, 360 and 390) that is substantially water resistant (hydrophobic, paragraph 104) comprising waxes such as carnauba wax, shellac, spermaceti, natural and synthetic waxes (inclusive of beeswax [natural] and Opaglos 6000® [synthetic], paragraph 259). It further discloses mannitol, dibasic calcium phosphate, microcrystalline cellulose, magnesium stearate and croscarmellose sodium (paragraph 248) and calcium carbonate (paragraph 242).

Patel et al. does not teach sumatriptan succinate.

Oxford teaches succinate is the preferred salt for the formulation of sumatriptan (column 3, lines 10-11) for oral administration (paragraph 13, line 61 to paragraph 14, line 47) for treatment of migraine headache (column 3, lines 12-18).

Patel et al. does not teach a product that is "free of degradation products with exposure of a 5-HT receptor agonist to ambient moisture", however, Patel et al. teach that spray congealing method is particularly suitable for moisture sensitive substances, since non-aqueous compositions can be utilized. It is completed before the product comes in contact with any equipment surface (paragraph 333). Hence since the composition of Patel is a core with a waxy coat the coat is employed with particular consideration to moisture sensitive substances, it meets the claim in that there are no degradation products therein. As noted in *In re Best* (195 USPQ 430 (CCPA 1977)), and *In re Fitzgerald* (205 USPQ 594 (CCPA 1980)), the mere recitation of newly-discovered function or property, inherently possessed by things in prior art, does not cause claims drawn to those things to distinguish over prior art. In such a situation, the burden is

shifted to the applicant to prove that subject matter shown to be in prior art does not possess characteristic relied on where it has reason to believe that functional limitation asserted to be critical for establishing novelty in claimed subject matter may be inherent characteristic of prior art; whether rejection is based on "inherency" under 35 U.S.C. 102, on "prima facie obviousness" under 35 U.S.C. 103, jointly or alternatively, burden of proof is same. Although the storage conditions are not disclosed in the prior art, Patel et al. teach an improved storage stability of the active ingredient (paragraph 284). Further, Remington's Pharmaceutical Sciences teach that one could extrapolate the results of an extreme storage conditions test using the Arrhenius equation to calculate longer storage stability based on normal conditions, i.e. room temperature and normal humidity (see figure 19-2 page 279 and pages 283-284). The examiner cannot calculate the storage stability Patel et al. because the specifics of the storage conditions test are not provided. However, it would have been obvious to one of ordinary skill in the art to calculate the storage stability of the composition motivated by the teaching of Remington's Pharmaceutical Sciences that the storage stability is predictable based on a linear Arrhenius plot. When the general conditions are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. In this case, it would have been obvious to one of ordinary skill in the art to predict the storage stability under various conditions motivated by the teaching of Patel et al. who teach substantially water resistant (hydrophobic, paragraph 104) 5-HT receptor agonist composition comprising, for example, sumatriptan, and waxes such as carnauba wax, shellac, spermaceti, natural and synthetic waxes (inclusive of beeswax [natural] and

Opaglos 6000® [synthetic], paragraph 259) and a moisture barrier coating (paragraph 47) and the teachings of Remington's Pharmaceutical Sciences who teach that storage stability is predictable based on a linear Arrhenius plot. Regarding instant claims 35-38, drawn to core materials, Patel et al. teach sumatriptan, mannitol (paragraph 220, 230, 247 and 248), calcium carbonate, dibasic calcium phosphate, microcrystalline cellulose, croscarmellose, sodium, and magnesium stearate (paragraph 248). The specific weight ratio of sumatriptan to excipients such as, mannitol, dibasic calcium phosphate, microcrystalline cellulose, croscarmellose and magnesium stearate is not specifically disclosed, However, Patel et al. teach that the ratio of excipients to active ingredient, e.g. sumatriptan is about 5-95 wt % and preferably 20-80 wt% based on the total weight of the formulation which overlaps with the instantly claimed amount of active agent of 20-55% sumatriptan succinate. "[A] prior art reference that discloses a range encompassing a somewhat narrower claimed range is sufficient to establish a prima facie case of obviousness." *In re Peterson*, 315 F.3d 1325, 1330, 65 USPQ2d 1379, 1382-83 (Fed. Cir. 2003). See also *In re Harris*, 409 F.3d 1339, 74 USPQ2d 1951 (Fed. Cir. 2005). In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.

Regarding claims 86 and 87 drawn to the process of making the oral formulation, Patel et al. teach the process of making an oral composition comprising a water resistant coated core (see supra) and further teach methods of wet granulation and

compression techniques (paragraphs 272). Tablets are disclosed in paragraph (229) (addressing instant claim 88).

Response to Arguments

Applicant states that the term "ambient moisture" has been removed, however the term still appears in instant claim 5 (see line 3 of the claim). Regarding the rejection of claims 1, 5-17, 31-34, 39-42, 61, 80-82 and 86-88 under 35 U.S.C. 103(a) as being unpatentable over Patel et al. U.S. Patent Application Publication No. 2003/0180352 A1 and Oxford U.S. Patent No. 5,037,845 and in view of Remington's Pharmaceutical Sciences, (1975), applicant states that the instant claims are patentable because the broad genus disclosed in the primary reference does not render obvious the Applicants' instantly claimed subject matter. Applicant asserts that Patel discloses compositions that may comprise at least 1500 active materials and at least 200 possible additional components, e.g. surfactants, substrates, solubilizers, antifoamers, etc. In response, Patel et al. teach sumatriptan (paragraphs 46, 60, 106-107, 447, and 448) for oral use (paragraph 272) comprising a core material (paragraphs 316, 350, 360 and 390) that is substantially water resistant (hydrophobic, paragraph 104) comprising waxes such as carnauba wax, shellac, spermaceti, natural and synthetic waxes (inclusive of beeswax [natural] and Opaglos 6000® [synthetic], paragraph 259). It further discloses mannitol, dibasic calcium phosphate, microcrystalline cellulose, magnesium stearate and croscarmellose sodium (paragraph 248) and calcium carbonate (paragraph 242). Patel et al. teach that spray congealing method is particularly suitable for moisture sensitive

substances, since non-aqueous compositions can be utilized. It is completed before the product comes in contact with any equipment surface (paragraph 333). Hence since the composition of Patel is a core with a waxy coat the coat is employed with particular consideration to moisture sensitive substances. "[I]n a section 103 inquiry, 'the fact that a specific [embodiment] is taught to be preferred is not controlling, since all disclosures of the prior art, including nonpreferred embodiments, must be considered.'" *Merck & Co. v. Biocraft Laboratories, Inc.,* 874 F.2d 804, 807 (Fed. Cir. 1989) (quoting *In re Lamberti,* 545 F.2d 747, 750 (CCPA 1976)); *see also In re Mills,* 470 F.2d 649, 651 (CCPA 1972) ("All the disclosures in a reference must be evaluated, including nonpreferred embodiments, and a reference is not limited to the disclosure of specific working examples." (citations omitted)). A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant. The degree of teaching away will of course depend on the particular facts; in general, a reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant. *In re Gurley,* 27 F.3d 551,553 (Fed. Cir. 1994). In this case, Patel et al. specifically disclose the problem of moisture sensitive substances and teach a waxy coat to protect the composition. Thus one would not be discouraged from following the path set out in the reference.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne (Bonnie) Eyler can be reached on (571) 272-0871. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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April 21, 2010